

Office of Regulatory Management
Economic Review Form

Agency name	Virginia Waste Management Board
Virginia Administrative Code (VAC) Chapter citation(s)	9VAC20-120 (repeal) 9VAC20-121 (new)
VAC Chapter title(s)	Regulated Medical Waste Management Regulations
Action title	Amendment 3
Date this document prepared	August 17, 2022

Cost Benefit Analysis

Table 1a must be completed for all actions. Tables 1b and 1c must be completed for actions (or portions thereof) where the agency is exercising discretion, including those where some of the changes are mandated by state or federal law or regulation. Tables 1b and 1c are not needed if **all** changes are mandated, and the agency is not exercising any discretion. In that case, enter a statement to that effect.

- (1) Direct Costs & Benefits: Identify all specific, direct economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (A direct impact is one that affects entities regulated by the agency and which directly results from the regulatory change itself, without any intervening steps or effects. For example, the direct impact of a regulatory fee change is the change in costs for these regulated entities.) When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo. One bullet has been provided, add additional bullets as needed.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of total (overall) direct costs described above.
 - (b) Enter estimated dollar value of total (overall) direct benefits described above.
 - (c) Enter the present value of the direct costs based on the worksheet.
 - (d) Enter the present value of the direct benefits based on the worksheet.
- (3) Benefits-Costs Ratio: Calculate d divided by c OR enter it from the worksheet.
- (4) Net Benefit: Calculate d minus c OR enter it from the worksheet.
- (5) Indirect Costs & Benefits: Identify all specific, indirect economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (An indirect impact is one that results from responses to the regulatory change, but which are not directly required by the regulation. Indirect impacts of a regulatory fee change on regulated entities could include a change in the prices they charge, changes in their operating procedures or employment levels, or decisions to enter or exit the regulated profession or market. Indirect impacts also include responses by other entities that have close economic ties to the regulated entities, such as suppliers or partners.) If there are no indirect costs or benefits, include a specific statement to that effect.

- (6) Information Sources: Describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
- (7) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct Costs & Benefits	<p style="text-align: center;"><u>Costs</u></p> <ul style="list-style-type: none"> • Public Universities and Other State Agencies- Public universities and state agencies (e.g. VDACS) with Regulated Medical Waste treatment units are considered particularly affected by the proposed amendments to the regulation. Additionally, there may be minor impacts on VDH, and DCLS as potential generators of RMW. (Please see Attachment A) No other state agencies are known to be particularly impacted by these regulations. • RMW generators, transfer stations, and RMW treatment facilities – RMW generators, transfer stations and treatment facilities located in the Commonwealth are considered particularly affected by the proposed amendments to the regulation. There are currently 16 permitted RMW transfer stations and treatment facilities in the Commonwealth. The proposed regulation also affects the universe of RMW generators which includes hospitals, doctor’s offices, clinics, and other healthcare facilities as well as veterinary establishments, labs, and research facilities, etc. The Agency does not have an estimate of the number of affected facilities under this category which likely includes a mix of small and large businesses. <p>For RMW generators, the proposed regulation includes an additional requirement for the maintenance of shipping papers that may have an on-going administrative cost to maintain records for three years after shipment.</p> <p>Additional requirements in the proposed regulation that may have additional cost associated with them include the following:</p> <p style="text-align: center;"><u>Permit</u></p> <p>New RMW Treatment and Transfer Facilities will apply for a PBR (Facilities with existing PBRs may have to update their current PBR under certain circumstances) (9VAC20-121-40(B) and 9VAC20-121-300). This process will also include public participation. Requirement for permit renewal every 10 years would be eliminated.</p>
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Estimated Cost of New Requirement: Permit Fee (for new facilities and modifications of existing permitted facilities , Cost of Publication of Notice in Newspaper of General Circulation (for new facilities), Potential cost of additional staff time (or hired consultant) to prepare application, Annual Fee

Handling, Operations

All RMW must be handled in a manner that maintains the integrity of the packaging at all times. Cart tippers, conveyors, etc. must control movement and impact to maintain integrity of packaging (9VAC20-121-100(F))

RMW Transfer stations or treatment facilities shall maintain and operate in accordance with a regulated medical waste management plan that meets all the requirements of 9VAC20-121-330 (9VAC20-121-230(B))

Each facility shall conduct monthly inspections of all major aspects of the facility and maintain records of inspections onsite (9VAC20-121-230(U))

RMW Transfer stations and treatment facilities shall implement an unauthorized waste control program (9VAC20-121-230(K))

Radiation detection equipment shall be operated and maintained in a manner that ensures that all incoming waste is screened and the measurements are meaningful and fulfill the objectives for detecting radiologically contaminated waste (9VAC20-121-230(L))

Estimated Cost of New Requirement: Potential retrofits for facilities using cart tippers or slides or conveyors to ensure the movement of RMW is controlled to maintain the integrity of the packaging, potential cost of installation of a fixed radiation detector, if applicable and not already in place voluntarily, potential cost of additional staff time to conduct and document inspections.

No additional costs associated with a waste management plan, or unauthorized waste program are expected. These elements were components of existing requirements that will be clarified by the proposed regulation.

Recordkeeping

All RMW Facilities must maintain records onsite of receipt, shipment or treatment of all RMW for at least three years (9VAC20-121-100(I)(a) and 9VAC20-121-340)

All RMW Facilities shall maintain a RMW management plan in the operating record (9VAC20-121-340(D))

All RWM Facilities shall maintain inspection logs (9VAC20-121-340(K))

All RMW Facilities shall keep records of all Unauthorized Waste (9VAC20-121-340(J))

Estimated Cost of New Requirement: Majority of proposed record keeping requirements clarify or rename already existing requirements. No additional costs are expected as a result of proposed recordkeeping requirements.

Treatment

Prior to operation of any treatment unit, the facility must conduct validation testing in accordance with 9VAC20-121-320 and an approved treatment plan to establish the appropriate operating parameters for effective treatment of RMW (9VAC20-121-240(B)(8) and 9VAC20-121-260).

Periodic challenge testing shall be performed under full loading in accordance with 9VAC20-121-270 to evaluate the effectiveness of each treatment unit and method (9VAC20-121-240(B)(9) and 9VAC20-121-270).

Estimated Cost of New Requirement:

Additional cost for validation requirements, including costs for 4 to 12 biological indicators for each of three validation test runs and approximately 8 hours of additional staff time to complete the testing.

Challenge testing includes costs of 0 to 3 additional biological indicators per month beyond the current requirement, depending on the volume of waste treated. The number of biological indicators per month corresponds to the volume of waste treated per load. Staff time for performing challenge tests is not anticipated to be lengthened by the use of additional biological indicators.

Benefits

- **Public Universities and Other State Agencies-** Staff may benefit from increased efficiencies due to clearer and more streamlined regulations.
- **RMW generators, transfer stations, and RMW treatment facilities** –Amendments to the regulation are intended to benefit RMW generators by streamlining and reorganizing the regulation for ease of use and better understanding of the requirements. Consolidation of generator and management requirements as well as updating requirements to reflect current industry standards will greatly benefit program staff and regulated entities. Specifically, the proposed removal of the following requirements may result in a cost savings to regulated facilities:
 - Removal of requirement to shred treated RMW
 - Flexibility for treatment facilities to establish operating parameters specific to the treatment unit and waste stream

	<p>rather than defaulting to general regulatory performance standards for a particular treatment method</p> <ul style="list-style-type: none"> ○ Multiple options for the effective cleaning and disinfection of reusable containers ○ Multiple options for packaging of treated RMW ○ Removal of permit expirations after 10 years and required renewals. Permits will now be valid for the life of the facility, consistent with the VSWMR ○ The addition of Category A waste management requirements will allow staff to better respond to the next emerging disease outbreak ○ Adding validation procedures and improving period challenge testing requirements for RMW treatment facilities provide the benefit of helping to identify and correct any compliance issues with ineffective or failing treatment equipment sooner than would be expected under the existing regulation. ○ Additional requirements for Category A Waste and testing of treatment units will also provide the benefit of better protections for human health ○ Overall the proposed regulation will better protect human health and lower the risk and cost of exposure as a result of improperly managed RMW. <p><u>Cost of Estimated Benefit:</u> Exact value of benefits is unknown at this time. Potential cost savings as a result of the proposed regulations include: saved staff time, elimination of potential civil charges, medical bills from potential exposures to RMW, potential cost of hiring a consultant. Based on information from NIH and the International Safety Center, total average medical costs associated with injuries and or illness from improper handling of sharps (31 incidents out of every 100 employees in 2021), as well as medical costs resulting from injuries and or illness associated with exposure to bodily fluids as a result of improper handling in 2021(11 incidents out of every 100 employees) cost approximately \$1,127,573 in 2021. By complying with regulations that are easier to understand and streamlined, it is estimated that employers could potentially benefit from an initial cost savings of approximately \$1,127, 573 in medical fees for injuries and illness associated with improper handling and management of RMW.</p>	
(2) Quantitative Factors	Estimated Dollar Amount	Present Value

Direct Costs	(a) Permit Fee- \$390 Public Notice Publication(Avg. of facilities most affected- \$200.00 Annual Fee- \$3,062.00 Cart Tipper Modification-\$0- 2,000 Radiation Detector-\$6,000- 8,000 Validation testing(at least once every 5 years-\$108-\$145 Challenge Testing-\$0-12 per month	(c) Total Present Value – 39,028	
Direct Benefits	(b) Potential benefits could include cost savings of medical bills associated with accidental exposure to infectious agents as a result of improper handling of RMW. Based on 2021 data, this could result in a cost savings of \$1,127, 573.	(d) Total Present Value- 1,127,573	
(3) Benefits- Costs Ratio	28.89	(4) Net Benefit	1,088,545
(5) Indirect Costs & Benefits	No indirect costs or benefits could be easily identified as a result of the proposed regulatory changes.		
(6) Information Sources	Current DEQ RMW PBR Permit Fee and RMW Annual Fees paid by regulated facilities, survey of regulated entities, Average cost of newspaper publication fee of regulated facilities, Online vendors of medical waste equipment (mcfenvironmental.com, consteryl.com, biosafeeng.com, globalindustrial.com, grainger.com, vitalitymedical.com, uline.com, bttusa.com, amscope.com, frontpointsecurity.com, synergymedco.com) Estimated Benefits- jhsph.edu, https://pubmed.ncbi.nlm.nih.gov , internationalsafetycenter.org/exposure-reports/		
(7) Optional			

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

This table addresses current requirements and the implications of not making any changes. In other words, describe the costs and benefits of maintaining the current regulatory requirements as is.

<p>(1) Direct Costs & Benefits</p>	<p><u>Permit</u> Main permitting costs associated with preparing an application, permit fee for either a PBR(onsite) or full PBR (offsite), annual fee dependent on how much RMW is generated, potential publication in newspaper of general circulation Estimated Cost of Requirement: Permit Fee, Cost of Annual Fee, Cost of Publication of Notice in Newspaper of General Circulation, Potential cost of additional staff time (or hired consultant) to prepare application</p> <p><u>Handling/Storage/Operations</u> Main RMW handling requirements include: personal protective equipment for staff handling RMW, sharps containers for contaminated sharps, spill kits which include enough absorbent material to absorb 10 gallons per kit, one gallon of disinfectant, 500 red bags, carts for internal handling, key card access/locked areas for RMW storage, separate refrigerator if needed, opaque/orange bags for treated waste, red biohazard bags for RMW, hospital grade disinfectant Estimated Cost of New Requirement: Includes: cost of enough PPE for all staff handling RMW, cost of contents of spill kit (multiple if needed) which includes PPE, absorbent material, red bags, and disinfectant, adequate number of sharp disposal containers, cost of key card access/locked or other similar system, cost of individual refrigerator, cost of opaque/orange bags, cost of red biohazard bags, cost of carts, cost of hospital grade disinfectant</p> <p><u>Recordkeeping /Packaging/Labeling</u> Recordkeeping/packaging and labeling requirements associated with treated and untreated RMW, treatment and general handling requirements Estimated Cost of New Requirement: Potential cost of a regulatory compliance officer in the healthcare industry to complete recordkeeping requirements and conduct training, etc.</p> <p><u>Treatment</u> Cost of treatment will be dependent on if the facility in question treats its RMW on site and is also dependent on type of treatment used. Treatment could include chemical treatment, incineration, steam sterilization, or other alternate treatment technologies. Estimated Cost of Requirement:</p>
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	<p>Cost of treatment dependent on method of treatment. Potential costs include: captial and maintenance costs associated with the treatment method employed.</p> <p><u>Closure & Financial Assurance</u> Cost of preparing closure plan, clean-up and removal of waste and treatment equipment, cost of FA mechanism, yearly adjustment of FA mechanism for inflation (FA required for privately owned facilities)</p> <p>Estimated Cost of Requirement: Cost of FA dependent on mechanism chosen and cost of closure of the facility in question</p>
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(2) Quantitative Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a) Permit Fee- \$390 or \$4,310 Public Notice Publication(Avg. of facilities most affected-\$200.00 Annual Fee- \$3,062.00 PPE-\$313 per person Sharps Containers- 2 gallon sharp container-\$4.83 per container, \$92.94 per pack of 20 Spill Kit Contents- PPE-\$313 per person, Absorbent Material-\$44 per 10 gallon capacity Disinfectant – 1 gallon- \$29 per year Red Bags- Max 500- \$954 Key Card System- \$100 per door Separate Fridge- \$982 Opaque/Orange Bags- 7-10 gallon bags- \$63.78 per 200 bags Red Bags- 10 gallon bags- \$190.74 for 100 bags Wheeled Cart- \$189 per cart Average Cost of Incinerator- \$40,000 Average Cost of Steam Sterilization Unit- \$35,000	(c) Total Present Value- 641,772,183

	Operating Costs of Incineration/Steam Sterilization- .25 to \$1.00 per pound of waste Average FA of currently permitted treatment facilities- \$19,000 Average FA of currently permitted transfer facilities- \$16,451	
Direct Benefits	(b) There are no quantifiable direct benefits from the current regulations.	(d) There are no quantifiable direct benefits from the current regulations.
(3) Benefits-Costs Ratio	0	(4) Net Benefit -641,772,183
(5) Indirect Costs & Benefits		
(6) Information Sources	Current DEQ RMW PBR Permit Fee and RMW Annual Fees paid by regulated facilities, survey of regulated entities, Average cost of newspaper publication fee of regulated facilities, Online vendors of medical waste equipment (mcfenvironmental.com, consteril.com, biosafeeng.com, globalindustrial.com, grainger.com, vitalitymedical.com, uline.com, bttusa.com, amscope.com, frontpointsecurity.com, synergymedco.com)	
(7) Optional		

Table 1c: Costs and Benefits under an Alternative Approach

This table addresses an alternative approach to accomplishing the objectives with different requirements. These alternative approaches may include the use of reasonably available alternatives in lieu of regulation, or information disclosure requirements or performance standards instead of regulatory mandates.

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> There are no readily discernible alternatives to the existing or proposed regulation. 	
(2) Quantitative Factors	Estimated Dollar Amount	Present Value

Direct Costs	(a)	(c)	
Direct Benefits	(b)	(d)	
(3) Benefits-Costs Ratio		(4) Net Benefit	
(5) Indirect Costs & Benefits			
(6) Information Sources			
(7) Optional			

Impact on Local Partners

- (1) Describe the direct costs and benefits (as defined on page 1) for local partners in terms of real monetary costs and FTEs. Local partners include local or tribal governments, school divisions, or other local or regional authorities, boards, or commissions. If local partners are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of total (overall) direct costs described above.
 - (b) Enter estimated dollar value of total (overall) direct benefits described above.
- (3) Indirect Costs & Benefits: Describe any indirect benefits and costs (as defined on page 1) for local partners that are associated with all significant changes. If there are no indirect costs or benefits, include a specific statement to that effect.
- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
- (5) Assistance: Identify the amount and source of assistance provided for compliance in both funding and training or other technical implementation assistance.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> • No localities are known to be particularly impacted by these regulations. Localities will continue to have a role in local zoning
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	decisions regarding the siting of RMW transfer stations and treatment facilities.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a)
Direct Benefits	(b)
(3) Indirect Costs & Benefits	
(4) Information Sources	
(5) Assistance	
(6) Optional	

Economic Impacts on Families

- (1) Describe the direct costs and benefits (as defined on page 1) to a typical family of three (average family size in Virginia according to the U. S. Census) arising from any proposed regulatory changes that would affect the costs of food, energy, housing, transportation, healthcare, and education. If families are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of direct costs.
 - (b) Enter estimated dollar value of direct benefits.
- (3) Indirect Costs & Benefits: Describe any indirect costs and benefits (as defined on page 1) to a typical family of three that are most likely to result from the proposed changes.
- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (5) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 3: Impact on Families

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> Families will not be particularly impacted by these regulations.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a)
Direct Benefits	(b)
(3) Indirect Costs & Benefits	
(4) Information Sources	
(5) Optional	

Impacts on Small Businesses

- (1) Describe the direct costs and benefits (as defined on page 1) for small businesses. For purposes of this analysis, “small business” means the same as that term is defined in § 2.2-4007.1. If small businesses are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of direct costs.
 - (b) Enter estimated dollar value of direct benefits.
- (3) Indirect Costs & Benefits: Describe the indirect benefits and costs (as defined on page 1) for small businesses that are most likely to result from the proposed changes.
- (4) Alternatives: Add a qualitative discussion of any equally effective alternatives that would make the regulatory burden on small business more equitable compared to other affected business sectors, and how those alternatives were identified.
- (5) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> Small businesses will not be affected by these regulations as the regulations pertain to RMW generators, transfer stations, and treatment facilities.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a)
Direct Benefits	(b)
(3) Indirect Costs & Benefits	
(4) Alternatives	
(5) Information Sources	
(6) Optional	

Changes to Number of Regulatory Requirements

For each individual VAC Chapter amended, repealed, or promulgated by this regulatory action, list (a) the initial requirement count, (b) the count of requirements that this regulatory package is adding, (c) the count of requirements that this regulatory package is reducing, (d) the net change in the number of requirements. This count should be based upon the text as written when this stage was presented for executive branch review. Five rows have been provided, add or delete rows as needed.

Table 5: Total Number of Requirements

Chapter number	Number of Requirements			
	Initial Count	Additions	Subtractions	Net Change
9VAC20-120	243	5(Self Inspections, Radiation Detector,	2(Shredding, Permit Expiration every 10 years)	3

		Cart Tippers, Validation, Challenge Testing)		
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COST BENEFIT ANALYSIS WORKSHEET

INTERIM v. July 28, 2022

Discount Rate:	3%	DO NOT CHANGE THIS NUMBER unless you wish to use a different
Time horizon:	10 years	

Notes:

1. Year 0 represents the current fiscal year
2. Options 1 & 2 below correspond to the two options in the grocery cart example. Option 3 below provides an
3. Replace the values in the green cells below with the expected costs and benefits for your analysis. Insert zero
4. The sections for options 2 and 3 must be filled out if the agency has any discretion over the proposed regulat

Year	Option 1		Option 2		Option 3	
	Cost	Benefit	Cost	Benefit	Cost	Benefit
0	13,941	1,127,573	73,093,630	0	0	0
1	3,206	0	73,037,580	0	0	0
2	3,206	0	73,037,580	0	0	0
3	3,206	0	73,037,580	0	0	0
4	3,206	0	73,037,580	0	0	0
5	3,351	0	73,037,580	0	0	0
6	3,206	0	73,037,580	0	0	0
7	3,206	0	73,037,580	0	0	0
8	3,206	0	73,037,580	0	0	0
9	3,206	0	73,037,580	0	0	0
TOTAL	42,940	1,127,573	730,431,850	0	0	0

Present Value						
Year	Option 1		Option 2		Option 3	
	Cost	Benefit	Cost	Benefit	Cost	Benefit
0	13,941	1,127,573	73,093,630	0	0	0
1	3,113	0	70,910,272	0	0	0
2	3,022	0	68,844,924	0	0	0
3	2,934	0	66,839,732	0	0	0
4	2,848	0	64,892,944	0	0	0
5	2,891	0	63,002,858	0	0	0
6	2,685	0	61,167,823	0	0	0
7	2,607	0	59,386,236	0	0	0
8	2,531	0	57,656,540	0	0	0
9	2,457	0	55,977,223	0	0	0
TOTAL	39,028	1,127,573	641,772,183	0	0	0

	Option 1	Option 2	Option 3
Benefit-Cost Ratio	28.89	0	#DIV/0!
Net Benefit	1,088,545	-641,772,183	0

ent discount rate; if so, please make a note of this on the Economic Impact form and provide a rationale

example where costs and benefits vary from year to year.

0 (0) for years where no costs or benefits are expected.

tory changes. Use "Option 2" for the status quo and "Option 3" for one other alternative.